

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

**Cellular, Tissue and Gene Therapies Advisory Committee (formerly the
Biological Response Modifiers Advisory Committee); Amendment of Notice**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Cellular, Tissue and Gene Therapies Advisory Committee (formerly the Biological Response Modifiers Advisory Committee). This meeting was announced in the **Federal Register** of January 27, 2005 (70 FR 3934). The amendment is being made to reflect the cancellation of the closed portion of the meeting and the following portions of the document: *Date and Time, Agenda, Procedure, and Closed Committee Deliberations*. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Gail Dapolito or Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512389. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 27, 2005, FDA announced that a meeting of the Cellular, Tissue and Gene Therapies Advisory Committee (formerly the Biological Response Modifiers Advisory Committee) would be held on March 3 and 4, 2005. On page 3935, in the first column,

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Revision Date 2-16-05
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the introductory paragraph, *Date and Time*, *Agenda*, and *Procedure* portions of the document are amended to read as follows:

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

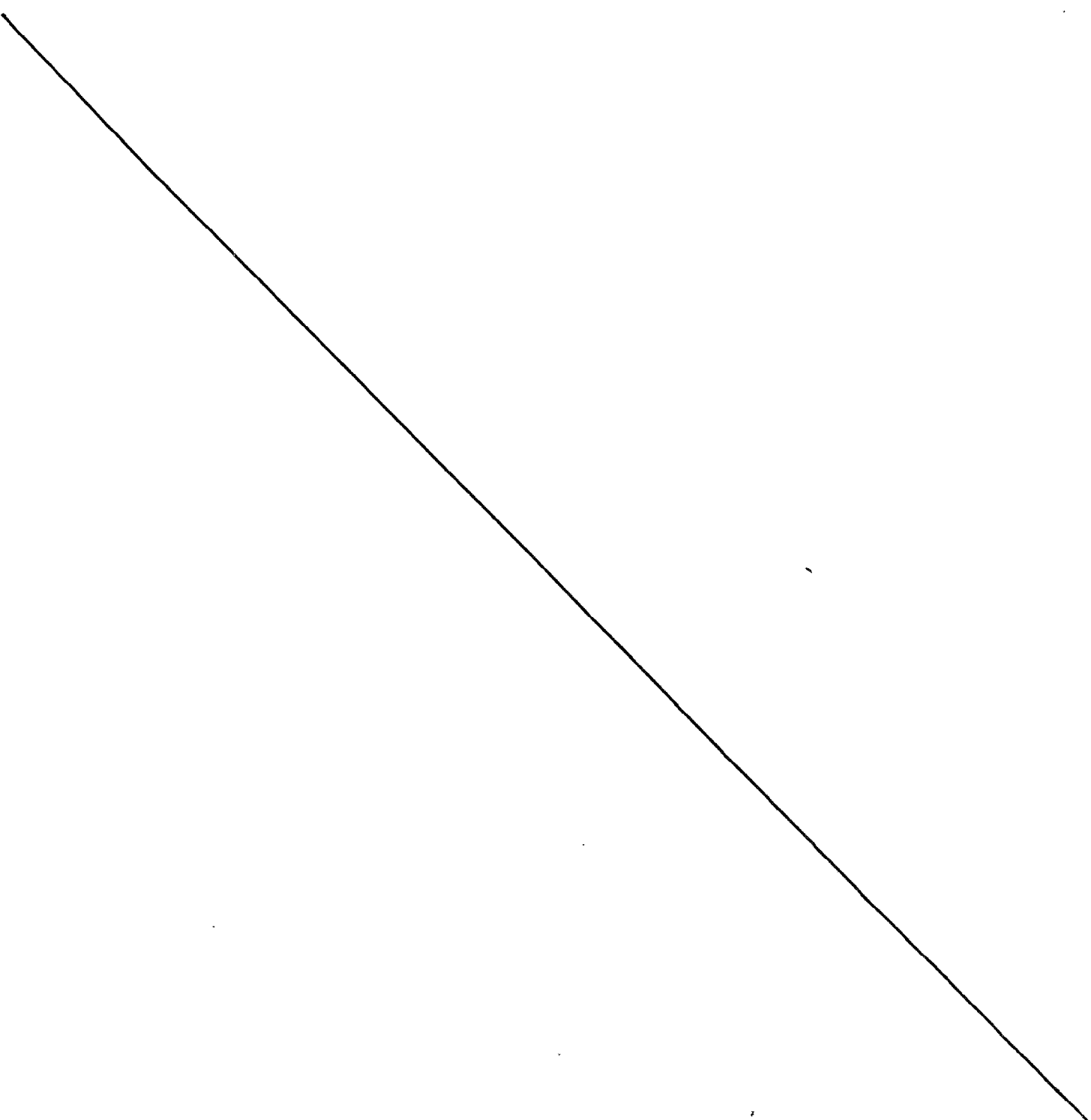
Date and Time: The meeting will be held on March 3, 2005, from 8 a.m. to approximately 6 p.m. and on March 4, 2005, from 8 a.m. to approximately 5 p.m.

Agenda: On March 3, 2005, all day and on March 4, 2005, in the morning, the committee will discuss cellular therapies for repair and regeneration of joint surfaces. Additionally, on March 4, 2005, the committee will discuss safety issues related to retroviral vector-mediated tumorigenesis in gene transfer clinical trials.

Procedure: On March 3, 2005, from 8 a.m. to approximately 6 p.m. and on March 4, 2005, from 8 a.m. to approximately 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 23, 2005. Oral presentations from the public will be scheduled on March 3, 2005, between approximately 11 a.m. and 11:30 a.m. and on March 4, 2005, between approximately 12 noon and 12:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 23, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

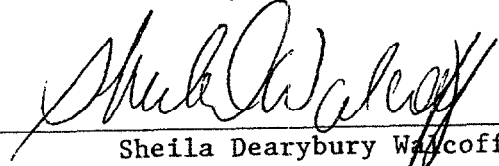
On page 3935, in the second column, the *Closed Committee Deliberations* portion of the document is deleted to reflect the cancellation of the closed portion of the meeting on March 3, 2005.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.



Dated: 2-8-05

February 8, 2005.



Sheila Dearybury Walcott,
Associate Commissioner for External Relations.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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